We claim:

1. A process for producing solid dosage forms which are suitable for oral or rectal administration for humans and animals, wherein

a) 0.5 to 30% by weight of at least one active ingredient,
b) 0.5 to 70% by weight of at least one cyclodextrin,
c) 10 to 98% by weight of at least one polymeric binder, selected from polyethylene glycol having a molecular weight above 1000, polyvinylpyrrolidone or copolymers comprising N-vinylpyrrolidone and vinyl acetate and
d) 0 to 50% by weight of conventional excipients.

are mixed and plasticized at a temperature below 220°C without adding a solvent and the resulting plastic mixture is shaped to the dosage form.

2. A process as claimed in claim 1, wherein the molar ratio between active ingredient and cyclodextrin is in the range from 0.1 to 4.0.

3. A process as claimed in any of the preceding claims, wherein the plastic mixture is shaped in a molding calender to dosage forms.

4. A process as claimed in claim 3, wherein a molding calender with counterrotating molding rolls is used, with at least one of the molding rolls having on its surface depressions to receive and shape the plastic mixture.

5. A solid dosage form which is essentially free of aliphatic C_2-C_8-di- and -tricarboxylic acids and aromatic C_6-C_{10}-monocarboxylic acids, obtainable by a process as claimed in any of claims 1 to 4.

6. A solid dosage form as claimed in claim 5, wherein at least 10% by weight of the active ingredient are present in the form of a cyclodextrin/active ingredient complex.

7. A process as claimed in any of the preceding claims, wherein polyethylene glycol, polyvinylpyrrolidone or copolymers comprising N-vinylpyrrolidone and vinyl acetate are employed as polymeric binder.

8. A solid dosage form which is essentially free of aliphatic C_2-C_8-di- and -tricarboxylic acids and aromatic C_6-C_{10}-monocarboxylic acids, obtainable by a process as claimed in any of claims 1 to 7.

9. A solid dosage form as claimed in claim 8, wherein at least 10% by weight of the active ingredient are present in the form of a cyclodextrin/active ingredient complex.

A process for producing solid cyclodextrin-containing dosage forms

Abstract

The present invention relates to a process for producing solid dosage forms comprising as components at least one physiologically tolerated polymeric binder, at least one active ingredient and at least one cyclodextrin, wherein the components are mixed and plasticized at a temperature below 220°C without adding a solvent and the resulting plastic mixture is shaped to the dosage form, and to the dosage forms obtainable by this process.